PRIMA LAB SA
Via Antonio Monti 7
6828 Balerna
Switzerland
www.primahometest.com

T. +41(0)91 605 1030
info@primalabsa.ch
CHE-301.179.156

www.histobox.com

Product Data
for
COVID-19 Rapid Test
Professional Use

an immunochromatographic assay for qualitative determination of specific IgG/IgM antibodies to COVID-19 in whole blood, serum or plasma specimen.

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1 Introduction

1.1/ Principle of the test and its intended use:

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to COVID-19 in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region, if the specimen contains IgG antibodies to COVID-19. A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to COVID-19, the conjugate-specimen complex reacts with anti-human IgM. A colored line appears in IgM test line region as a result.
Therefore, if the specimen contains COVID-19 IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains COVID-19 IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain COVID-19 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

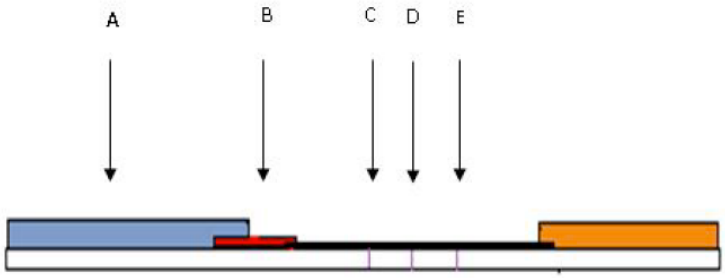

Figure 1: test principle

As shown in illustration in Fig. 1, the specimen (A) migrates via capillary action along the membrane to react with the gold conjugate (B). COVID-19 IgG or/and IgM present in the specimen binds to the conjugate, forming a colored COVID-19 antibody-antigen complex.
The mouse anti-human IgG and mouse anti-human IgM immobilized in the test zone of the membrane captures the test region (C) and test region (D). The formation of a visible colored line in the test region indicates a positive result (C) or (D). The absence of a colored line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (E) confirms control line.

Incubation Time: RESULTS AT 10 MINUTES.

Storage:
Store the test at 2-30°C. Do not freeze.

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Active ingredient list:

- Mouse anti-human IgG (capture reagent)
- Mouse anti-human IgM (capture reagent)
- Mouse IgG
- Goat anti-mouse IgG
- COVID-19 antigen (detection reagent)

Inactive ingredients list:

- Adhesive plastic backing
- Buffer
- Label pad
- Absorbent pad
- Sample pad
- Nitrocellulose membrane
- Desiccant (in pouch)
- Pouch
- Sample dropper

1.2/Assay procedure (for fingerstick whole blood specimen):

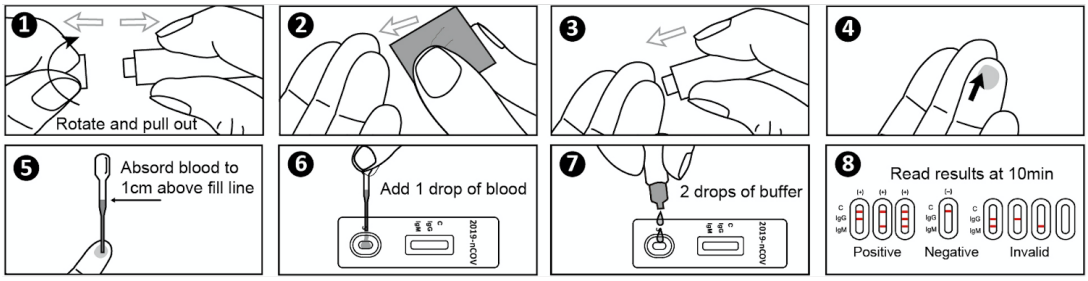

Figure 2: test procedure

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry. **Fig1 and Fig2.**
- Massage the hand by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the finger with a sterile lancet. Wipe away the first sign of blood. **Fig3.**
- Gently rub the hand from wrist to palm and then to finger to form a rounded drop of blood over the puncture site. **Fig4.**
- Take the pipette without pressing the bulb and place it in contact with the drop of blood. The blood will enter into the pipette by capillary action. Continue massaging your finger until the blood has reached the black line on the pipette (approximately 20µL). Avoid moving it away from the finger as much as you can, in order to prevent the formation of air bubbles. **Fig5.**
- Squeeze the bulb to dispense the whole blood to the specimen well of the test cassette. **Fig6.**
- Dispense two drops of diluent to the specimen well of the test cassette. **Fig7.**
- Read test results at 10 minutes. Do not interpret the result after 20 minutes. **Fig8.**

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1.3/Precautions:

- Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.
    - Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
    - Place the test cassette on a clean and level surface.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as anticoagulants.

1.4/ Interpretation of the results:

IgG POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

IgG and IgM POSITIVE:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

*NOTE: The intensity of the color in the test line regions may vary depending on the concentration of COVID-19 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgG region and IgM region.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

1.5/ Limitations:

- The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to COVID-19 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to COVID-19 can be determined by this qualitative test.
- **The COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to COVID-19 in the specimen and should not be used as the sole criteria for the diagnosis of COVID-19 infections.**
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. **A negative result at any time does not preclude the possibility of COVID-19 infection.**
- The hematocrit level of the whole blood can affect the test results. **Hematocrit level needs to be between 25% and 65% for accurate results.**

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2/Performance Study:

2.1/ Accuracy, specificity, sensitivity and correlation

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with a leading commercial PCR; the results show that COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity. Results for IgG and IgM are shown in Table 1 and 2 respectively.

Table 1: Performance of IgG specimen

Method		PCR		Total result
Rapid test cassette	Results	Positive	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total result		20	50	70

Specificity = 98.0% (95%CI: 89.4%~99.9%);

Sensitivity = 100% (95%CI: 86.0%~100%);

Accuracy = 98.6% (95%CI: 92.3%~99.96%).

Table 2: Performance of IgM specimen

Method		PCR		Total result
Rapid test cassette	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total result		20	50	70

Specificity = 96.0% (95%CI: 86.3%~99.5%);

Sensitivity = 85.0% (95%CI: 62.1%~96.8%);

Accuracy = 92.9% (95%CI: 84.1%~97.6%).

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) products have been compared with a commercial PCR using clinical specimen. The results show that the accuracy of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.6% for IgG and 92.9% for IgM.

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2.2/ Interferences

Analytes were spiked into negative specimen at the following concentrations listed. The specimens were tested in triplicate with visual interpretations occurring at 10 minutes after specimen application. Results are presented in table below.

Table 3: Interfering substances

Substance	Conc.	Lot : COV20010001-R		
		Negative		
Triglyceride	50mg/dl	-	-	-
Hemoglobin	1000mg/dl	-	-	-
Ascorbic Acid	20mg/dl	-	-	-
Total cholesterol	6mmol/l	-	-	-
Bilirubin	60mg/dl	-	-	-
Substance	Conc.	Lot : COV20010001-R		
		IgG positive		
Triglyceride	50mg/dl	+	+	+
Hemoglobin	1000mg/dl	+	+	+
Ascorbic Acid	20mg/dl	+	+	+
Total cholesterol	6mmol/l	+	+	+
Bilirubin	60mg/dl	+	+	+
Substance	Conc.	Lot : COV20010001-R		
		IgM positive		
Triglyceride	50mg/dl	+	+	+
Hemoglobin	1000mg/dl	+	+	+
Ascorbic Acid	20mg/dl	+	+	+
Total cholesterol	6mmol/l	+	+	+
Bilirubin	60mg/dl	+	+	+

Note: "-" mean negative result, "+"mean positive result

No substances showed any interference with the test. There were no differences observed between the results at 10 minutes.

2.3/ Cross-reactivity

Anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens as confirmed by ELISA or other method were tested with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) occurred at 10 minutes and 20 minutes after specimen application**.** Results were presented in Table below.

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Table 4: Cross reactivity table

Specimen	INCP-402	COV20010001-R	
		10min	20min
3 Anti-influenza A virus positive samples	1	-	-
	2	-	-
	3	-	-
3 Anti-influenza B virus positive samples	1	-	-
	2	-	-
	3	-	-
3 anti-HIV Positive Samples	1	-	-
	2	-	-
	3	-	-
3 anti-HCV Positive Samples	1	-	-
	2	-	-
	3	-	-
3 anti-Syphilis Positive Samples	1	-	-
	2	-	-
	3	-	-
3 HBsAg Positive Samples	1	-	-
	2	-	-
	3	-	-
3 Anti-RSV Positive Samples	1	-	-
	2	-	-
	3	-	-
3 Anti-Adenovirus Positive Samples	1	-	-
	2	-	-
	3	-	-
3 Anti-H.pylori Positive Samples	1	-	-
	2	-	-
	3	-	-

Note: "-" mean negative result

There was no cross-reaction with anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens at 10 and 20 minutes.

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2.4/ Hematocrit flex

Whole blood standards were prepared with type "O" red cell and COVID-19 specimen at the hematocrit 25%, 40%, 50% and 65%. Negative specimen was performed individually at different hematocrit. Visual interpretations were recorded at 20 minutes after specimen application.

Table 5. Hematocrit flex

Sample / Hematocrit	Negative		
25%	-	-	-
40%	-	-	-
50%	-	-	-
65%	-	-	-
Sample / Hematocrit	IgG positive		
25%	+	+	+
40%	+	+	+
50%	+	+	+
65%	+	+	+
Sample / Hematocrit	IgM positive		
25%	+	+	+
40%	+	+	+
50%	+	+	+
65%	+	+	+

Note: "-" mean negative result, "+" mean positive result

Flowing and background: Four different hematocrit levels showed good flow characteristics and the control line appeared within 3 mins. There was no background problem at read time even with the high hematocrit level.

There were no performance effects seen with the hematocrit levels testing. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) showed good flow and no background problem between 25% and 65% hematocrit.

2.5/ Anticoagulant study

Blood from 10 volunteers was collected with blank tube, EDTA-K2, Heparin sodium, Citrate sodium and Oxalate potassium anticoagulant tube. Whole blood and plasma were separated from the specimen in anticoagulant tube. The 10 negative specimens were tested with COVID-19 IgG/IgM Rapid Test Cassette (WB/Serum/Plasma). The tests were performed according to the package insert.

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Table 6. Anticoagulant study

EDTA-K2 Anticoagulant Tube			
Specimen No.	**Lot: COV20010001-R**		
	Negative		
	Whole Blood	**Plasma**	**Serum**
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-
5	-	-	-
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-
Heparin Sodium Anticoagulant Tube			
Specimen No.	**Lot: COV20010001-R**		
	Negative		
	Whole Blood	**Plasma**	**Serum**
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-
5	-	-	-
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-

Citrate Sodium Anticoagulant Tube			
Specimen No.	**Lot1: COV20010001-R**		
	Negative		
	Whole Blood	**Plasma**	**Serum**
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-

5	-	-	-
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-
Oxalate Potassium Tube			
Specimen No.	**Lot1: COV20010001-R**		
	Negative		
	Whole Blood	**Plasma**	**Serum**
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-
5	-	-	-
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-

Note: "-" mean negative results

The result showed no difference among different anticoagulant tube to collect whole blood specimens and plasma specimen in this study.

2.5/ Between day reproducibility

COVID-19 negative specimens were run individually on 3 separate days using the same lot of COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma). Results were rated visually as negative or positive at 10 minutes and 20 minutes after specimen application. Results are presented in table below.

Table 7. Between day results

Day 1 Results						
Lot	Negative					
COV20010001-R	1		2		3	
	10 min	20 min	10 min	20 min	10 min	20 min
	-	-	-	-	-	-
Day 2 Results						
Lot	Negative					
	1		2		3	

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	10 min	20 min	10 min	20 min	10 min	20 min
COV20010001-R	-	-	-	-	-	-
Day 3 Results						
Lot	Negative					
COV20010001-R	1		2		3	
	10 min	20 min	10 min	20 min	10 min	20 min
	-	-	-	-	-	-
Day 1 Results						
Lot	IgG positive					
COV20010001-R	1		2		3	
	10 min	20 min	10 min	20 min	10 min	20 min
	+	+	+	+	+	+
Day 2 Results						
Lot	IgG positive					
COV20010001-R	1		2		3	
	10 min	20 min	10 min	20 min	10 min	20 min
	+	+	+	+	+	+
Day 3 Results						
Lot	IgG positive					
COV20010001-R	1		2		3	
	10 min	20 min	10 min	20 min	10 min	20 min
	+	+	+	+	+	+

Day 1 Results						
Lot	IgM positive					
COV20010001-R	1		2		3	
	10 min	20 min	10 min	20 min	10 min	20 min
	+	+	+	+	+	+
Day 2 Results						
Lot	IgM positive					
COV20010001-R	1		2		3	
	10 min	20 min	10 min	20 min	10 min	20 min
	+	+	+	+	+	+
Day 3 Results						
Lot	IgM positive					
COV20010001-R	1		2		3	
	10 min	20 min	10 min	20 min	10 min	20 min
	+	+	+	+	+	+

Note: "-" mean negative result, "+" mean positive result

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The entirety of the results (100%) were consistent with expected results. No distinct difference was detected in intra lots.

3/ Accelerated stability data:

Accelerated Stability of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was evaluated using samples from 1 batch. These were placed in an incubator with the temperature calibrated at 45℃ and 55℃. Relative humidity (RH) calibrated at about 60%. A series of stability tests were performed for 0, 7 and 14 days for at about 45 ℃ or 55 ℃, according to Arrhenius Plot. See Table in below. Test cassettes were assayed using negative specimen. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert. Results are presented in Table below.

Arrhenius Formula:
In K=-Ea/RT + In A

"K" means Rate constant
"A" mean Arrhenius constant
"Ea" mean Activation energy
"R" mean Gas constant
"T" mean Temperature in Kelvin

Table 4: Timeline for accelerated stability study

Day / Temp.	0day	7days	14 days	21 days	28 days	35 days	42 days	56 days	77 days	84 days
45℃	×	×	×	×	×	×	×	×	×	×
55℃	×	×	×	×	×	×	×			

Table 5: 45℃ accelerated stability study

Day	Specimen	COVID-19 IgG/IgM Rapid Test Cassette		
		COV20010001-R		
0	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
7	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
14	Negative	-	-	-
	IgG positive	+	+	+

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	IgM positive			
21	Negative			
	IgG positive			
	IgM positive			
28	Negative			
	IgG positive			
	IgM positive			
35	Negative			
	IgG positive			
	IgM positive			
42	Negative			
	IgG positive			
	IgM positive			
56	Negative			
	IgG positive			
	IgM positive			
77	Negative			
	IgG positive			
	IgM positive			
84	Negative			
	IgG positive			
	IgM positive			

Table 6: 55℃ accelerated stability study

Day	**Specimen**	**COVID-19 IgG/IgM Rapid Test Cassette**		
		COV20010001-R		
0	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
7	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
14	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
21	Negative			
	IgG positive			
	IgM positive			
28	Negative			
	IgG positive			
	IgM positive			

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35	Negative			
	IgG positive			
	IgM positive			
42	Negative			
	IgG positive			
	IgM positive			

Note: "-" mean negative result, "+" mean positive result

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is stable at 45 ℃ for 14 days and at 55℃ for 14 days, the whole study will be finished at about middle of April 2020.

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4/Summary of Technical Specifications

Analytical method	**Immunochromatographic assay based onto a sandwich technique (Lateral Flow device)**
Sample	Whole blood – Serum - Plasma
Diluent	Yes
Sample collection	Disposable capillary pipette – venous blood collection tube
Sample volume per test	20 µl (for whole blood) – 10 µl for serum
Diluent volume per test	2 drops
Testing time	10 minutes
Test reading	Visual (Negative 1 line – Positive 2 lines)
Sensitivity	IgG: 100% and IgM: 85%
Specificity	IgG: 98% and IgM: 96%
Overall Accuracy	IgG: 98.6% and IgM: 92.9%
Kit storage	+ 2 + 30°C
Shelf-life	24 months from manufacturing date
Interferences and Cross reactions	No interferences and cross reactions have occurred during testing.

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